

EXHIBIT 1

Systemic Nanoparticle Albumin-Bound Paclitaxel (nab-Paclitaxel) for the Prevention of In-Stent Restenosis (SNAPIST-II): A Randomized Comparison of Single Dose and Single Dose Plus Repeat Dose at 2 Months

JE MacDonald^a, P Klinke^a, A Fung^b, D Ricci^c, C Suciu^d, F Orta^e, M Ursu^f, B Mut-Vitcu^d, C Dima^d, I Benedek^g, T Hinte^g, R Capalneau^h, S Morⁱ, M Dorobantu^g, S Balanescu^g, R Niculescu^g, J Margolis^h, R Waksmanⁱ, A Clawsonⁱ, S Rushⁱ, N Desai^j, D Hilton^k

^aVictoria Heart Institute Foundation, Victoria, British Columbia, Canada, ^bVancouver General Hospital, Vancouver, British Columbia, Canada, ^cCardiovascular Diseases and Transplant Institute, Targu-Mures, Romania, ^dCardiovascular Diseases Institute, Timisoara, Romania, ^eEmergency Clinical County Hospital, Targu-Mures, Romania, ^fNiculae Stancioiu Heart Institute, Cluj Napoca, Romania, ^gEmergency Clinical Hospital, Bucharest, Romania, ^hMiami International Cardiology Consultants, Miami, Florida, ⁱWashington Hospital Center, Washington, DC, ^jAmerican BioScience, Inc., Santa Monica, California

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Background: Safety of a single IV injection of nab-paclitaxel (ABI-007; CoroxaneTM) after de novo coronary stenting was established in SNAPIST-I (MacDonald, 2005). SNAPIST-II was initiated to compare the safety and efficacy of 1 versus 2 doses of nab-paclitaxel in patients with up to 2 stented lesions (≤ 25 mm length) in up to 2 de novo coronary arteries (≥ 2.5 mm diameter).

Methods: Patients were randomly assigned to IV treatment with either 1 dose of nab-paclitaxel 35 mg/m² immediately after successful, uncomplicated stenting or 1 dose at stenting plus a second dose 2 months later. Patients received aspirin and clopidogrel for 6 months. Primary endpoints were the safety of nab-paclitaxel and major adverse cardiac events (MACE: death, myocardial infarction [MI], coronary artery bypass grafting [CABG], target lesion revascularization [TLR], and target vessel revascularization [TVR]) at 2 months. Secondary endpoints were MACE and quantitative coronary angiographic (QCA) evaluation of restenosis at 6 months.

Results: Seventy-six patients (86% men, 11% with diabetes) aged 58 \pm 10 years were enrolled. QCA at baseline (available for 75 patients, 81 lesions) showed reference vessel diameter 2.90 \pm 0.54 mm, lesion length 10.16 \pm 3.49 mm, and vessel minimum luminal diameter (MLD) 1.08 \pm 0.47 mm pre-procedure and stent-MLD 2.77 \pm 0.44 mm post-stenting. Only 1 serious toxicity (gastrointestinal bleeding) was considered possibly related to study drug. Most side effects were mild. No MACE were observed at 2 months; preliminary MACE at 6 months were TLR (6/73) and TVR (7/73). No patient died or had an MI or CABG on study. Treatment-related adverse events with a frequency of $\geq 3\%$ and MACE are reported for the two dose groups in the table below.

	1 Dose	2 Doses	p value
No. of treated patients (n)	38	38	
Drug Safety (n=76)			
Nausea	4(11%)	1(3%)	0.358
Fatigue	1(3%)	3(8%)	0.615
Lymphopenia	1(3%)	2(5%)	>0.999
Mild hair loss (scalp or body)	2(5%)	1(3%)	>0.999
MACE 2 month (n=76)	0/38	0/38	
Preliminary MACE at 6 month (n=73)	2/37	5/36	0.261
TLR	2/37	4/36	0.430
TVR	2/37	5/36	0.261

Conclusions: nab-Paclitaxel administered IV at 35 mg/m² (1 or 2 doses) appears to be well tolerated with no significant differences in drug safety. TLR/TVR rates were encouraging. Although not statistically significant, preliminary 6-month MACE data showed fewer TLR/TVR for the single dose group. However, this needs to be verified by QCA. Complete data including 6-month QCA for the two groups will be available for presentation.